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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/218,913	12/22/1998	RODERICK L. HALL	98.736	2461

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EXAMINER

NASHED, NASHAAT T

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/18/2003

32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/218,913

Applicant(s)
Hall et al.

Examiner
Nashaat T. Nashed

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 26, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 11-13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14, and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 30 6) ☐ Other:

The application has been amended as requested in the communication filed March 26, 2003. Accordingly, claims 19-37 have been canceled, and claims 1, 12-15 and 18 have been amended. It is presumed that the applicants intended to amend claim 10 because the word "physiologically" is removed in both version of the claims, but the claim is labeled as "original". Thus, the amendment to claim 10 has been entered.

Claims 1-10, 14, and 16-18 are under consideration as they pertain to SEQ ID NO: 52.

New formal drawings are required in this application for the reasons set forth in the prior Office action, paper number 29. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the Patent and Trademark Office no longer prepares new drawings. **The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rasche *et al.* [IDS, paper number 16, reference number 7, *Arzneimittel-Forschung* 25 (1) 110-116 (1975)] for the reasons set forth in the prior Office action, paper number 29.

In response to the above rejections, Applicants argue that the cited reference does not disclose every element of the claim because they do not teach a method for accelerating mucocilliary clearance as presented in the instant claims.

Applicants' arguments filed 3/26/03 have been fully considered but they are not deemed to be persuasive. The specification defines the phrase "mucocilliary dysfunction" as the inability of ciliated epithelium to clear mucus and sputum in lung airway which is a serious complication of chronic obstructive lung diseases such as chronic bronchitis (CB), bronchiectasis, asthma, and specially, cystic fibrosis (CF), see page 1, lines 14-17. Rasche *et al.* teach the use of aprotonin, a Kunitz-type serine protease, to treat an obstructive lung disease such obstructive bronchitis and emphysema, see the paragraph bridging pages 1 and 2. Also, they teach that a shortage of local protease inhibitors can arise in the bronchial area causing chronic obstruction in the airways for many years. The

results obtained Rasche *et al.* clearly show that the application of the protease inhibitor relive the dysfunction and improve the patent conditions. It appears that the drop of in airway resistance and the liquefaction of viscous sputum are clinical observation resulting from accelerating mucocilliary clearance, I. e., increasing the clearance of mucus and sputum from the lung airway. Applicants have not presented any evidence or indeed any argument indicating that the drop of airway resistance and the liquefaction of viscous sputum are not related to the acceleration of mucocilliary clearance.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 3-10 are rejected under 35 U.S.C. § 103 as being unpatentable over Rasche *et al.* [IDS, paper number 16, reference number 7, *Arzneimittel-Forschung* 25 (1) 110-116 (1975)] in view of the state of the art for the reasons set forth in the prior Office action, paper number 29.

In response to the above rejections, Applicants argue that the examiner failed to establish a *prima facie* case of obviousness because Rasche *et al.* does not suggest an

accelerated rate of mucocilliary clearance by administering a composition comprising a Kunitz-type serine protease inhibitor.

Applicants' arguments filed 3/26/03 have been fully considered but they are not deemed to be persuasive. The examiner agrees with the applicants that Rasche *et al.* does not suggest an accelerated rate of mucocilliary clearance by administering a composition comprising a Kunitz-type serine protease inhibitor. Rasche *et al.* teach the claimed method, and provide one of ordinary skill in the art with a motivation to deliver the pharmaceutical composition directly to the airways. They write (see last paragraph of the translated document on page 7):

We based this on our investigations and of other authors who showed that most biochemical reactions which leads to airway obstruction occur locally in the bronchial area, and therefore would be better influenced by inhalation therapy. Inhalation therapy encompasses all means of administering drug to the airways such as aerosol, aerosol suspension, and powder inhaler which can be delivered by any kind of nebulizer, and non-toxic propellant. The ordinary skill in the art would have had the experience, and the knowledge to formulate any chemical compound in an aerosol, aerosol suspension or dry powder inhaler and the means to deliver them as evident by the availability of many drugs on the market in these forms. Also, Rasche *et al.* provide one of ordinary skill in the art with an expectation of success as they teach a method of treating chronicle bronchitis with Kunitz-type inhibitor. Thus, the examiner have met his burden by establishing a *prima facie* case of obviousness.

Claims 14, and 16-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Delaria *et al.* (J. Biol. Chem. 1997, 272 (18), 12209-12214) in view of the state of the art as exemplified by Rasche *et al.* [IDS, paper number 16, reference number 7, *Arzneimittel-Forschung* 25 (1) 110-116 (1975)], Fritz *et al.* (U. S. Patent 5,407,915), and O'Riordan *et al.* (IDS: Am. J. Respir. Crit. Care Med Vol. 155, pp. 1522-1528) for the reasons set forth in the prior Office action, paper number 29.

In response to the above rejections, Applicants traverse the rejection on the ground that the examiner has engaged in hindsight reconstruction based on applicants' disclosure. Also, applicants attempt to discredit each individual reference by indicating that they do not teach the invention.

Applicants' arguments filed 3/26/03 have been fully considered but they are not deemed to be persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and

does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The cited prior art clearly contains all the teaching required to carry out the claimed invention including the amino acid sequence of SEQ ID NO: 52. Also, the prior art provides motivation to incorporate all the elements of the claimed invention. Fritz *et al.* motivate one of ordinary skill in the art to use human proteins having low molecular weight such as bikunin. Delaria *et al.* provide one of ordinary skill in the art with motivation to use the placental bikunin expressed in mammalian cells in the pharmaceutical composition as they teach a water soluble glycosylated human bikunin. Rasche *et al.* teach a method of treating chronic bronchitis with Kunitz-type serine protease inhibitor, see above. As indicated by the applicant O'Riordan *et al.* suggested that elastase inhibitor may be useful in protecting against mucociliary dysfunction, see page 41 of the response to the first Office action. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, clearly *prima facie* obvious.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 13, and 16-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 15-18 of copending Application No. 09/441,966 (966) for the reasons set forth in the prior Office action, paper number 29.

In response to the above rejection, Applicants have not traversed the above rejection or filed a terminal disclaimer. They have requested to hold the rejection in

abeyance until allowable subject matter is indicated. The rejection will remain on record until further action by the applicants.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Nashaat T. Nashed, Ph. D.
Primary Examiner